37

Supreme Court, U.S.
FILED
MAY 23 2007
OFFICE OF THE CLERK

(4)

No. 06-179

In the Supreme Court of the United States

CHARLES R. RIEGEL AND
DONNA S. RIEGEL, PETITIONERS

v.

MEDTRONIC, INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

PAUL D. CLEMENT
Solicitor General
Counsel of Record
PETER D. KEISLER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
MALCOLM L. STEWART
Assistant to the Solicitor General
DOUGLAS N. LETTER
SHARON SWINGLE
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

DANIEL MERON
General Counsel
SHELDON T. BRADSHAW
Associate General Counsel
Department of Health and Human Services
Rockville, MD 20857

QUESTION PRESENTED

Whether, under the express preemption provision in 21 U.S.C. 360k, the Food and Drug Administration's premarket approval of a medical device preempts state-law tort claims relating to the safety or efficacy of the device.

TABLE OF CONTENTS

Page

Statement 1
Discussion 7
A. The decision of the court of appeals is correct 8
B. The decision of the court of appeals does not warrant review 18
Conclusion 20

TABLE OF AUTHORITIES

Cases:

Bates v. *Dow Agroscis. LLC*, 544 U.S. 431 (2005) 12, 14, 15, 16, 19
Brooks v. *Howmedica, Inc.*:
535 U.S. 1056 (2002) 20
273 F.3d 785 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002) 18
Collagen Corp. v. *Green*, 520 U.S. 1212 (1997) 20
Fry v. *Allergan Med. Optics*:
522 U.S. [illegible] (1997) 20
695 A.2d 511 (R.I.), cert. denied, 522 U.S. 952 (1997) 18
Goodlin v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) 18
Green v. *Dolsky*:
520 U.S. 1168 (1997) 20
685 A.2d 110 (Pa. 1996), cert denied, 520 U.S. 1168, and 520 U.S. 1212 (1997) 18

Cases—Continued: Page

Horn v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) 17, 18

Kemp v. *Medtronics, Inc.*:

534 U.S. 818 (2001) 20

231 F.3d 216 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001) 18

Knisley v. *Medtronic, Inc.*: 126 S. Ct. 420 (2005) 20

Martin v. *Medtronic, Inc.*:

534 U.S. 1078 (2002) 20

234 F.3d 573), (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002) 18

McMullen v. *Medtronic, Inc.*:

126 S. Ct. 1464 (2006) 20

421 F.3d 482 (7th Cir. 2005), cert. denied, 126 S. Ct. 1464 (2006) 18

Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) ..... *passim*

Niehoff v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 523 U.S.C. 1005 (1998) 19

Oja v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) 19

Smith Indus. Med. Sys., Inc. v. *Kernats*, 522 U.S. 1044 (1998) 16

State ex rel. Miller v. *New Womyn, Inc.*, 679 N.W.2d 592 (Iowa 2004) 19

Weiland v. *Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999) 18

Cases—Continued: Page

Worthy v. *Collagen Corp.*:
524 U.S. 954 (1998) 20
967 S.W.2d 360 (Tex.), cert. denied, 524 U.S. 954 (1998) 18

Statutes and regulations:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* 1
21 U.S.C. 331(a)-(c) 14
21 U.S.C. 352(a) 14
21 U.S.C. 352(j) 14
21 U.S.C. 360(k) 2
Medical Device Amendments, 21 U.S.C. 360c *et seq.* 1
21 U.S.C. 360c(a)(1) 2
21 U.S.C. 360c(a)(1)(C) 2
21 U.S.C. 360c(a)(2) 3
21 U.S.C. 360c(a)(2)(B) 11
21 U.S.C. 360c(a)(2)(C) 11
21 U.S.C. 360e(a)(1) (2000 & Supp. IV 2004) 2
21 U.S.C. 360e(b)(1)(A) 2
21 U.S.C. 360e(c)(1) 2
21 U.S.C. 360e(d)(1)(A) 3, 11, 16
21 U.S.C. 360e(d)(1)(B) 3
21 U.S.C. 360e(d)(2)(A) 3

Statutes and regulations—Continued: Page

21 U.S.C. 360e(d)(2)(A)-(E) 11
21 U.S.C. 360e(d)(2)(B) 3
21 U.S.C. 360e(d)(2)(D) 3
21 U.S.C. 360e(d)(6) 3
21 U.S.C. 360e(e)(1)(A) 12
21 U.S.C. 360e(e)(1)(B) 12
21 U.S.C. 360e(e)(1)(F) 12
21 U.S.C. 360j(e)(1) 3
21 U.S.C. 360k 8, 17, 19
21 U.S.C. 360k(a) 4, 12, 15, 16, 19
21 U.S.C. 360k(a)(1) 5, 11, 13
21 U.S.C. 360k(a)(2) 13
21 U.S.C. 360k(b) 4, 16
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136v(b) 14
21 C.F.R.:
Section 14.171 2
Section 814.20 2
Section 814.20(b)(13) 2
Section 814.39 3
Section 814.39(d) 3
Section 814.39(d)(1) 3
Section 814.39(d)(2) 3
Section 814.44(d)(1) 3
Section 814.45(c) 2
Section 814.80 3
Section 814.82 3

Miscellaneous: Page

62 Fed. Reg. (1997):
p. 65,384 17
p. 65,387 17
63 Fed. Reg. 39,789 (1998) 17
71 Fed. Reg. 3935 (2006) 17

In the Supreme Court of the United States

No. 06-179

CHARLES R. RIEGEL AND
DONNA S. RIEGEL, PETITIONERS

v.

MEDTRONIC, INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States. In the view of the United States, the decision of the court of appeals is correct and does not warrant review by this Court.

STATEMENT

1. This case presents the question whether premarket approval of a Class III medical device by the Food and Drug Administration (FDA) preempts state-law tort claims premised on allegations that the device in question is unsafe or ineffective. The device at issue in this litigation—the Evergreen Balloon Catheter—is a medical device regulated by the FDA pursuant to the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* The FDCA identifies three classes of medical

devices, each subject to a different level of regulation. See 21 U.S.C. 360c(a)(1); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 476-477 (1996). The Evergreen Balloon Catheter is a Class III device, see 21 U.S.C. 360c(a)(1)(C), and is accordingly subject to the most stringent regulatory controls. With exceptions that are not implicated here, the manufacturer of a Class III device must obtain FDA approval of a premarket approval (PMA) application before marketing the device. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); *Lohr*, 518 U.S. at 477.[1]

In order to obtain premarket approval for a Class III medical device, a manufacturer must submit a PMA application containing full reports of investigations of the device's safety and effectiveness; a statement of the components and principles of operation of the device; a comprehensive description of the methods of manufacture, processing, packing, and installation of the device; and the proposed labeling for the device. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20. In determining whether to approve a PMA application, the FDA considers the information submitted by the manufacturer as well as other information known to the agency. See 21 C.F.R. 814.45(c). The FDA may also request additional information from the manufacturer, and it may consult with a scientific advisory committee made up of outside experts. 21 C.F.R. 14.171, 814.20(b)(13). The agency conducts a rigorous

---

[1] As the Court explained in *Lohr*, see 518 U.S. at 477-478, two categories of Class III devices may be marketed without PMA approval by the FDA. First, devices that were already being marketed for use at the time of the MDA's enactment may continue to be marketed until the FDA issues an applicable regulation requiring submission of a PMA. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); 21 U.S.C. 360e(b)(1)(A); *Lohr*, 518 U.S. at 477-478. Second, a new device that is "substantially equivalent" to a device that is already lawfully on the market may enter the market through FDA clearance of a premarket submission commonly referred to as a "510(k)." See 21 U.S.C. 360(k); *Lohr*, 518 U.S. at 478. Those provisions of the FDCA do not apply in this case, since the Evergreen Balloon Catheter is a post-MDA device for which PMA approval was required.

review of requests for premarket approval, devoting an average of 1200 hours to each application. See *Lohr*, 518 U.S. at 477.

The FDA grants premarket approval for a Class III device only if, *inter alia*, the agency finds that there is a "reasonable assurance of safety and effectiveness" when the device is used in accordance with the conditions of use included in the proposed labeling, and that the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A); see 21 U.S.C. 360e(d)(2)(A), (B) and (D). In determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The FDA may impose restrictions on the sale or distribution of the device as a condition of premarket approval, see 21 U.S.C. 360e(d)(1)(B); 21 C.F.R. 814.82, and it may impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1). After a manufacturer has received premarket approval for a Class III medical device, it must submit a supplemental application to the FDA before making any changes to the device that affect the device's safety or effectiveness. See 21 U.S.C. 360e(d)(6); 21 C.F.R. 814.39, 814.80. With narrow exceptions, the manufacturer must receive the FDA's approval before making any such changes.[2]

---

[2] For a narrow class of changes, the manufacturer may submit a "Changes Being Effected" application, setting out in detail the proposed change and the data or information that supports it. See 21 C.F.R. 814.39(d). Unless the FDA rejects the "Changes Being Effected" application within a specified period, the manufacturer may implement the proposed change prior to FDA action on the application, see 21 C.F.R. 814.39(d)(1), although the FDA retains the authority to reject the application and to require the manufacturer to stop distributing the product with the change. Among the types of changes that are eligible for a "Changes Being Effected" application are labeling changes that add or strengthen a warning, as well as changes in quality control or manufacturing process that provide additional assurance of purity, identity, strength, or reliability of the device. See 21 C.F.R. 814.39(d)(2).

The FDCA contains an express preemption provision. That provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). The FDA is authorized to exempt from preemption certain State or local requirements for a device. See 21 U.S.C. 360k(b).

2. The Evergreen Balloon Catheter is a Class III medical device manufactured by respondent Medtronic, Inc. Pet. App. 3a. It is used during angioplasties to open patients' clogged arteries. *Ibid.* The device received premarket approval from the FDA in 1994. *Ibid.* In 1995 and 1996, the FDA approved respondent's supplemental applications for revised labeling for the device. *Id.* at 3a-4a.

Petitioner Charles Riegel suffered extensive injuries after an Evergreen Balloon Catheter ruptured while he was undergoing angioplasty. Pet. App. 4a. He and his wife, petitioner Donna Riegel, brought suit in federal court against respondent. *Ibid.* Petitioners' complaint alleged negligent design, testing, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium. *Id.* at 4a-5a. The district court held that all of petitioners' claims except those for negligent manufacturing and breach of express warranty were preempted by 21 U.S.C. 360k(a). See Pet. App. 55a-74a. The court subse-

quently granted respondent's motion for summary judgment on the merits of the non-preempted claims. *Id.* at 75a-91a.

3. The court of appeals affirmed. Pet. App. 1a-54a.

The court of appeals explained that the premarket approval process for Class III medical devices is "lengthy and rigorous," requiring each manufacturer to provide extensive information establishing the safety and effectiveness of its device. See Pet. App. 8a-9a. The court further observed that "[t]here is significant opportunity for interaction between the FDA and the manufacturer over the course of the PMA process," *id.* at 8a, and that the FDA is authorized to impose additional requirements as conditions of premarket approval in order to ensure that the device is safe and effective, *id.* at 9a. The court explained as well that, once the FDA approves an application for premarket approval, federal law requires the manufacturer to comply with the specifications set forth in the application and the approval order. See *ibid.*

In holding that the bulk of petitioners' claims were preempted, the court of appeals construed the term "requirement" in 21 U.S.C. 360k(a)(1) to encompass product specifications set forth in the PMA application that was submitted by respondents and approved by the FDA. See Pet. App. 26a-28a. The court explained that, if the FDA had viewed respondent's proposed product specifications as inadequate to ensure safety and efficacy, the agency could have imposed additional requirements as conditions of premarket approval. *Id.* at 27a-28a. The court recognized that the approved specifications for the Evergreen Balloon Catheter had been fashioned by respondent rather than devised by the FDA, see *id.* at 28a, but it found that fact to be irrelevant to the preemption analysis. The court explained that, "[o]nce the PMA process is complete, all PMA-approved devices are subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications." *Ibid.*

The court of appeals further held that the imposition of tort liability based on the allegedly defective character of the device would have the practical effect of subjecting the manufacturer to state-law requirements "different from, or in addition to," the federal requirements embodied in the approved PMA application. Pet. App. 32a, 35a-36a. The court noted that the claims held to be preempted "do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the approved PMA application for the Evergreen Balloon Catheter." *Id.* at 32a. Rather, the court explained,

> a verdict in [petitioners'] favor on any of these claims would represent a finding that the Evergreen Balloon Catheter had not adhered to the various state common law duties implicated by those claims, *e.g.*, that its design did not comport with the duty of due care, or that its labeling did not comport with the duty to warn. Such a verdict would clearly differ from the FDA's PMA approval of the device (and its related packaging, labeling, distribution, and so on) as being reasonably safe and effective, and, moreover, from the FDA's prohibition against making any modifications affecting the device's safety and effectiveness without first obtaining FDA approval.

Id. at 33a. The court further noted that its conclusion that such tort claims are preempted is supported by the FDA's position on the preemption question. *Id.* at 37a-38a.

The court of appeals also concluded that the FDA's grant of premarket approval is significantly different, for purposes of preemption analysis, from the substantial-equivalence determination (see note 1, *supra*) that was at issue in *Lohr*. See Pet. App. 24a-27a. The court noted that premarket approval, unlike a finding of substantial equivalence, reflects the FDA's considered judgment that there is reasonable assurance that the device

at issue is safe and effective. See *id.* at 25a. The court further observed that, whereas a substantial-equivalence finding "does not reflect the FDA's determination that the device should 'take any particular form for any particular reason,' the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective." *Id.* at 26a (quoting *Lohr*, 518 U.S. at 493). The court also explained that manufacturers of devices for which a substantial-equivalence finding has been made "have broader latitude to make changes without FDA approval than do manufacturers of PMA[-]approved devices." *Id.* at 26a-27a.[3]

Judge Pooler filed an opinion concurring in part and dissenting in part. Pet. App. 43a-54a. While characterizing the preemption issue presented in this case as a "close question," *id.* at 43a, Judge Pooler would have held that petitioners' claims are not preempted, see *id.* at 50a-53a.

DISCUSSION

The court of appeals correctly held—in accordance with the FDA's interpretation of the FDCA, see Pet. App. 37a-38a—that the FDA's premarket approval of a Class III medical device imposes federal "requirements" that preclude the imposition of state-law tort liability based on respondent's alleged failure to

---

[3] The court of appeals "agree[d] with the district court's conclusion that [petitioners'] negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a. The court explained that "[a] jury verdict in [petitioners'] favor on this claim would not have imposed state requirements that differed from, or added to, the PMA-approved standards for this device, but would instead have simply sought recovery for [respondent's] alleged deviation from those standards." *Id.* at 35a-36a. The court of appeals affirmed the district court's grant of summary judgment to respondent on the merits of the negligent-manufacturing claim, however, see *id.* at 38a-43a, and petitioners do not challenge that ruling in this Court.

satisfy inconsistent or additional state-law requirements. The Second Circuit's decision in this case accords with the large majority of federal and state appellate rulings on the question presented here. Although one federal court of appeals and one state supreme court have held that comparable tort claims were not preempted, those decisions predate most of the other cases addressing the question, and they were issued without the benefit of FDA's current judgment that premarket approval of a Class III device imposes federal "requirements" that should be given preemptive effect. In light of those intervening developments, the courts that have previously rejected preemption defenses in this context may reconsider their position in an appropriate case. This case, moreover, would not be an appropriate vehicle in which to address the preemption of state tort suits concerning Class III devices that have received PMA approval. See pp. 14-15, *infra*. Review by this Court therefore is not warranted.

A. The Decision Of The Court Of Appeals Is Correct

Petitioners contend (Pet. 19-22) that the court of appeals' ruling in this case is inconsistent with this Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). *Lohr*, however, does not govern this case.

1. In *Lohr*, this Court considered the application of the MDA's express preemption provision, 21 U.S.C. 360k, to a tort suit involving a medical device for which the FDA had made a substantial-equivalence determination. See 518 U.S. at 480-481. In rejecting the manufacturer's claim that the suit was preempted, the Court explained that the process by which substantial-equivalence findings are made "is by no means comparable to the PMA process," involving an average of 20 hours of review time in contrast to the 1200 hours spent on the average PMA review. *Id.* at 478-479. The Court also noted the FDA's own admonition that its substantial-equivalence determination

"should not be construed as an endorsement of the [device]'s safety." *Id.* at 480.

The manufacturer in *Lohr* argued that the FDA's promulgation of general standards for labeling and manufacturing of medical devices "pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." 518 U.S. at 486 (plurality opinion). All Members of this Court agreed that the statute does not impose that blanket prohibition on the imposition of state-law tort liability. See *id.* at 487 (plurality opinion); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The manufacturer also argued, *inter alia*, that the FDA's clearance of a device based on a substantial-equivalence determination preempted suits alleging that the device was defectively designed. See *id.* at 492 (opinion of the Court). In rejecting that contention, the Court explained that "[t]he company's defense exaggerates the importance of the [substantial-equivalence] process," *ibid.*, and that the device at issue had "never been formally reviewed [by the FDA] under the MDA for safety or efficacy," *id.* at 493. Accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

A four-Justice plurality of the *Lohr* Court predicted that any common-law suits preempted by Section 360k would be "few" and "rare." 518 U.S. at 502. In his concurring opinion, however, Justice Breyer stated that "ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care imposed by a state-law tort action." *Id.* at 504-505. Justice Breyer further stated that he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Id.* at 508. The remaining four Justices "conclude[d] that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements

would differ from those imposed by the [FDCA]." *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Those Justices also expressed disagreement with the plurality's forecast that instances of such preemption would be "rare." *Ibid.* Thus, five Members of the Court in *Lohr* agreed that state tort suits are preempted on essentially the same terms as state prescriptive requirements.

The Court in *Lohr* also noted the significant role of the FDA in defining the MDA's preemptive scope. The Court explained:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941), and, therefore, whether it should be pre-empted.

518 U.S. at 496 (footnote omitted). The Court concluded that, with respect to the construction of the FDCA's express preemption provision, "[t]he ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a sound basis for giving substantial weight to the agency's view of the statute." *Ibid.* (citation and internal quotation marks omitted).

2. In the instant case, the court of appeals held that the FDA's premarket approval of the Evergreen Balloon Catheter imposed specific federal "requirements" that preempted inconsistent duties sought to be imposed through application of state tort law. See Pet. App. 25a-29a. That holding is correct and is consistent with this Court's decision in *Lohr*.

The FDA's premarket approval for the Evergreen Balloon Catheter was premised on the agency's finding that there was reasonable assurance that the device was safe and effective under the conditions of use prescribed, recommended, or suggested

in the labeling of the device and that the labeling was neither false nor misleading. 21 U.S.C. 360c(a)(2)(B), 360e(d)(1)(A) and (2)(A)-(E); see Pet. App. 25a, 27a-28a. Once the device was approved, moreover, respondent could not lawfully implement any changes that would affect the safety or efficacy of the device without submitting a supplemental application to the FDA (and, in most instances, receiving prior FDA approval). See *id.* at 26a; p. 3 and note 2, *supra*. Because the specifications contained in respondent's application were binding on the manufacturer once the application had been approved, and because the FDA's PMA approval reflected the agency's considered judgment as to the product's safety and efficacy, the court of appeals correctly held that those specifications constitute federal "requirement[s]" within the meaning of Section 360k(a)(1).

Moreover, in determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The court of appeals' ruling thus is fully consistent with *Lohr*, in which the Court distinguished the facts before it from a case, such as this one, "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers." 518 U.S. at 501.

As the court of appeals explained, if the FDA had determined that the device as described in respondent's application was not safe and effective, the agency could have conditioned its grant of premarket approval on respondent's agreement to undertake specified modifications. Pet. App. 27a-28a. A product specification devised by the FDA and imposed as a condition of authority to market a medical device would constitute a federal "requirement" that would preempt state efforts to impose inconsistent or

additional common-law duties. The court of appeals correctly recognized that respondent should not be subject to *greater* potential tort liability simply because the FDA had "deemed the PMA application for the Evergreen Balloon Catheter acceptable in its present form" and therefore had declined to impose additional conditions. *Id.* at 28a.

The FDCA also specifically addresses the possibility that new information might come to light that would call into question whether a previously approved device meets the Act's requirements for PMA approval. Once again, however, the FDCA vests responsibility for taking action in the FDA, based on its evaluation of the information and weighing of the relevant considerations. The Act thus authorizes the FDA to withdraw its PMA approval of a device if the agency finds that the device is unsafe or ineffective, or if the agency finds, on the basis of new information evaluated together with information available to it when it approved the application, that the requisite showing of reasonable assurance that the device is safe and effective is lacking, or that the labeling is false or misleading in any particular and was not corrected within a reasonable time after receipt from the FDA of notice of that fact. See 21 U.S.C. 360e(e)(1)(A), (B) and (F). Where the FDA has not taken such action, its approval of the PMA—and the "requirements" that result from that approval—remain in effect.

The court of appeals also correctly held that petitioners' tort suit seeks to impose state "requirement[s]," within the meaning of Section 360k(a), that relate to safety or efficacy and are different from the federal requirements that apply to the Evergreen Balloon Catheter. See Pet. App. 30a-35a. As the court of appeals recognized, this Court in construing similarly worded federal preemption provisions "has held firm to the view that state 'requirements' can be created by state common law actions." *Id.* at 31a; see, *e.g.*, *Bates* v. *Dow Agroscis. LLC*, 544 U.S. 431, 443 (2005); see also *Lohr*, 518 U.S. at 503-504 (Breyer, J., concur-

ring in part and concurring in the judgment); *id.* at 510-512 (O'Connor, J., concurring in part and dissenting in part). The claims that the court of appeals held to be preempted do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the specifications in the approved PMA application. Rather, they all rest on the allegation that the Evergreen Balloon Catheter, in the form approved by the FDA, "is in some way defective and therefore requires modification." Pet. App. 32a. A verdict in petitioners' favor would necessarily reflect a finding that respondent could comply with applicable state-law duties of care only by altering the product specifications or labeling that had been reviewed and approved by the FDA. Imposition of tort liability on the basis of such a finding would entail the application of state-law requirements that are "different from, or in addition to," 21 U.S.C. 360k(a)(1), the federal requirements applicable to the device, and that "relate[] to the safety or effectiveness of the device," 21 U.S.C. 360k(a)(2).

The FDA is the expert agency charged by Congress with balancing the risks and benefits of medical devices under the FDCA, and the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application. When the FDA has concluded that a particular medical device is safe and effective for use and has approved the device for marketing, it would undermine the regulatory scheme established by Congress for a jury adjudicating a state-law claim to determine that the same device is defectively designed. Similarly, when the FDA concludes that a particular warning label strikes an appropriate balance between properly notifying users of potential dangers and ensuring that beneficial and possibly life-saving uses of the device are not deterred, a jury should be precluded from deciding that different warnings ought to have been given.

3. In *Bates*, this Court construed the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b) (quoted in *Bates*, 544 U.S. at 439). FIFRA prohibits the sale of "misbranded" products and states that a pesticide is misbranded if its labeling contains "false or misleading" statements, "does not contain adequate instructions for use," or "omits necessary warnings." *Bates*, 544 U.S. at 438. That misbranding prohibition applies to pesticides that are registered with the Environmental Protection Agency (EPA). *Ibid.* The Court held in *Bates* that FIFRA did not preempt the plaintiffs' state-law damages claim alleging a tortious failure to warn so long as the elements of the state cause of action were substantively equivalent to FIFRA's prohibition on the sale of "misbranded" products. See *id.* at 447. The Court "emphasize[d]," however, that "a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453.

The FDCA also prohibits the distribution of misbranded devices, see 21 U.S.C. 331(a)-(c), and a device is deemed misbranded if, *inter alia*, "its labeling is false or misleading in any particular," or the device "is dangerous to health when used in the * * * manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 352(a) and (j). The misbranding prohibition applies to products that have received PMA approval. The federal requirements that result from the PMA process have preemptive effect, however, and as explained below, the possibility of federal misbranding liability does not alter that result. See pp. 15-16, *infra*. In any event, petitioners in their certiorari petition do not advance the theory that their state-law claims are preserved because the relevant state-law requirements parallel the FDCA's

misbranding provisions. Cf. note 4, *infra*. Indeed, petitioners do not even cite the FDCA's misbranding provisions. Nor did the court of appeals address that issue; it considered only whether the PMA approval process itself results in "requirement[s]" under 21 U.S.C. 360k(a), and whether state common law imposes corresponding state "requirement[s]." This case therefore would not present an occasion for the Court to consider the viability of such a theory.

Such a theory would be unavailing in any event. The process of agency review under FIFRA with regard to the label language at issue in *Bates* differs in important respects from the process by which the FDA decides whether to grant premarket approval for particular Class III devices. The plaintiff farmers in *Bates* alleged that the label of a pesticide manufactured by the defendant had failed to warn of the potential for the pesticide to damage the farmers' peanut crops. See 544 U.S. at 434-435. Under FIFRA, EPA reviews pesticides and their labeling to determine whether the pesticide causes unreasonable adverse effects on human health or safety or the environment, but EPA does not evaluate the efficacy of the product, including its potential to harm crops or cause other property damage, and the agency does not review the accuracy of any statements about efficacy on the proposed labeling for the product. *Id.* at 440. EPA therefore had not determined whether the label at issue in *Bates* had adequately warned farmers of the potential for damage to their crops. See *ibid.* (noting that EPA had "never passed on the accuracy of the statement in [the pesticide's] original label recommending the product's use 'in all areas where peanuts are grown'"). In the instant case, by contrast, petitioners' challenge to the safety and efficacy of the Evergreen Balloon Catheter goes directly to matters as to which the FDA conducted a rigorous agency review in the PMA process—a review that culminated in the FDA's finding that the Evergreen Balloon Catheter *does* provide "reasonable assurance of safety and effectiveness"

and that the labeling is not "false or misleading." See 21 U.S.C. 360e(d)(1)(A).[4]

Furthermore, the Court explained in *Bates* that FIFRA does not have a comprehensive goal of "uniformity," but rather "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450. Under the FDCA, by contrast, the FDA is vested with centralized authority in order to promote uniformity of regulation, including the authority under 21 U.S.C. 360k(b) to decide whether exceptions to preemption of state law should be allowed.

4. In its amicus brief filed at the petition stage at the Court's invitation in *Smith Industries Medical Systems, Inc.* v. *Kernats*, cert. denied, 522 U.S. 1044 (1998), the United States took the position that the FDA's grant of premarket approval for a medical device does not itself establish federal "requirement[s]" for the device within the meaning of Section 360k(a). U.S. Br. at 14-17, *Kernats*, *supra* (No. 96-1405). The position taken in the government's brief in *Kernats* was based upon the FDA's interpretation of the MDA and the agency's characterization of its role in the administrative process at that time, as reflected in a pro-

---

[4] As a general matter, 21 U.S.C. 360k(a) does not preempt common-law suits in which the duty of care is defined by federal law and a State simply provides additional remedies for violations of the federal standard. See *Lohr*, 518 U.S. at 494-497; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Consistent with that principle, the court of appeals correctly held that petitioners' "negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a; see note 3, *supra*. Adjudication of the negligent-manufacturing claim would not implicate any FDA finding, since the agency has made no individualized determination whether a particular catheter conforms to the approved product specifications. With respect to the adequacy of the product specifications themselves, however, the FDA found that there was reasonable assurance of safety and effectiveness of the device, and that the labeling was not false or misleading, when it approved respondent's PMA application.

posed interpretive rule that was appended to the brief and published shortly after the brief was filed. See 62 Fed. Reg. 65,384, 65,387 (1997). That proposed rule, however, was subsequently withdrawn. See 63 Fed. Reg. 39,789 (1998).

The FDA has since reexamined the issue and determined that the position it announced at the time of the filing in *Kernats* was erroneous. The FDA's current position was set forth in an amicus brief filed by the United States on May 14, 2004, in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). See *Horn*, 376 F.3d at 170-173 (discussing the FDA's position set forth in the amicus filing). The government explained in the amicus brief in *Horn* that the prior position did not adequately reflect either the highly detailed nature of the process by which the FDA reviews applications for premarket approval, or the constraints that premarket approval places on manufacturers who subsequently wish to change a device's specifications. U.S. Amicus Br., *Horn* v. *Thoratec*, *supra*, at 28 (No. 02-4597); see generally *id.* at 6-11, 15-17, 20-21, 25-27. The government's position in *Kernats* is also inconsistent with the risk-management principles that the FDA currently follows, which recognize that over-warning may be detrimental to the public health. See, *e.g.*, *id.* at 29; 71 Fed. Reg. 3935 (2006) (explaining that additional state requirements governing disclosure of drug-risk information "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use," and that "[e]xaggeration of risk could discourage appropriate use of a beneficial drug"). This Court held in *Lohr* that the FDA's views on preemption questions under 21 U.S.C. 360k are entitled to "substantial weight." 518 U.S. at 496.

B. The Decision Of The Court Of Appeals Does Not Warrant Review

The Second Circuit's resolution of the preemption question raised in this case is consistent with the rulings of the great majority of federal and state appellate courts that have addressed the issue since *Lohr*. During that period, all but one of the federal courts of appeals to decide the issue have held that premarket approval of a medical device preempts state tort claims challenging the safety or efficacy of a product that was designed, manufactured, and labeled in compliance with the terms of the premarket approval order. See Pet. App. 24a-38a; *Horn*, 376 F.3d at 166-180; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 486-490 (7th Cir. 2005), cert. denied, 126 S. Ct. 1464 (2006); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 575-585 (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 221-237 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001); see also *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 791-799 (8th Cir. 2001) (en banc) (finding federal preemption based on approval of device pursuant to regulatory precursor of premarket approval process), cert. denied, 535 U.S. 1056 (2002); but see *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1369-1382 (11th Cir. 1999) (holding that comparable claims were not preempted). Similarly, all but one of the state supreme courts to rule on this issue have held that analogous suits are preempted by federal law. See *Green* v. *Dolsky*, 685 A.2d 110, 115-118 (Pa. 1996), cert. denied, 520 U.S. 1168, and 520 U.S. 1212 (1997); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 514-517 (R.I.), cert. denied, 522 U.S. 952 (1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 366-377 (Tex.), cert. denied, 524 U.S. 954 (1998); but see *Weiland* v. *Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151-1154 (Ill. 1999).[5]

---

[5] Petitioners contend that three additional cases are in conflict with the weight of authority holding that the FDA's premarket approval of a medical

Moreover, the decisions in *Goodlin* and *Weiland*, which rejected preemption defenses similar to that raised by respondent here, were issued in 1999, when the law in this area was relatively undeveloped and when the stated view of the FDA, as set forth in the amicus brief filed by the United States in *Kernats* (see pp. 16-17, *supra*), was that the PMA approval process does not impose "requirement[s]" under 21 U.S.C. 360k(a) and that claims like petitioners' were not preempted. Since that time, several federal courts of appeals and state supreme courts have sustained analogous preemption defenses, and no such court has issued a contrary ruling. And since that time, the FDA has reassessed the issue and has concluded that the PMA approval process does result in "requirements" and that state tort claims challenging the safety or efficacy of PMA-approved devices are therefore preempted under 21 U.S.C. 360k(a). See p. 17, *supra*.

The courts in *Goodlin* and *Weiland* had no opportunity to take into account the later-developing majority view among the federal and state appellate courts. Nor did the courts in *Goodlin* and *Weiland* have the opportunity to consider the current position of the FDA, the expert agency charged by Congress with administering the FDCA. In any future decision concerning Section 360k's preemptive scope, those courts would be required

---

device preempts state tort claims under Section 360k(a). See Pet. 3 (citing *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Nichoff* v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 523 U.S. 1005 (1998)); Pet. 14 (citing *State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004)). Those cases are readily distinguishable. None of them involved devices for which the FDA had approved a PMA application before the conduct that was alleged to be the basis for liability. See *Oja*, 111 F.3d at 787, 789; *Nichoff*, 950 S.W.2d at 817; *New Womyn*, 679 N.W.2d at 597. In *Oja* and *Nichoff*, moreover, the courts held that liability under state tort law or other state law of general applicability would not result in the imposition of a state "requirement," see *Oja*, 111 F.3d at 789; *Nichoff*, 950 S.W.2d at 822—a premise that was subsequently rejected by this Court in *Bates*, see 544 U.S. at 443; p. 12, *supra*.

to give "substantial weight" to the FDA's position. *Lohr*, 518 U.S. at 496.

In light of those intervening developments, the Eleventh Circuit and the Illinois Supreme Court may reconsider their earlier approach should this issue arise in future cases litigated within those jurisdictions. Under these circumstances, the narrow split in authority does not warrant this Court's review. This Court has repeatedly denied certiorari petitions that presented questions concerning the preemptive effect of the FDA's issuance of premarket approval for Class III medical devices. See *McMullen* v. *Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks* v. *Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001); *Worthy* v. *Collagen Corp.*, 524 U.S. 954 (1998); *Fry* v. *Allergan Med. Optics*, 522 U.S. 952 (1997); *Green* v. *Dolsky*, 520 U.S. 1168 (1997); *Collagen Corp.* v. *Green*, 520 U.S. 1212 (1997). There is no reason for a different result here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

PAUL D. CLEMENT
Solicitor General

PETER D. KEISLER
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

MALCOLM L. STEWART
Assistant to the Solicitor General

DOUGLAS N. LETTER
SHARON SWINGLE
Attorneys

DANIEL MERON
General Counsel

SHELDON T. BRADSHAW
Associate General Counsel
Department of Health and Human Services

MAY 2007